removing at least a portion of the first joint surface to expose a cancellous bone surface;

forming a cavity into the medullary canal of the [exposed] cancellous bone carrying the second joint surface;

selecting a bioresorbable implant configured to fit between the first and second joint surfaces, the implant having a face, a backside and a stem portion extending from the backside and configured to fit within said cavity;

inserting the stem portion into the cavity and placing the bioresorbable implant between the first and second joint surfaces so the implant initially keeps said [exposed cancellous bone surface] surfaces spaced apart [from the second joint surface] and the face is slidably movable relative to the first joint surface; and

using the joint, including slidably moving the face relative to the first joint surface;

whereby the cancellous bone surface initially forms fibroblast which progresses into fibrocartilage as the implant is resorbed so the fibrocartilage effectively replaces the implant during such resorption.

REMARKS:

Claims 1-6, 8-10 and 24-26 are pending.

Attached for the convenience of the Examiner is a clean "Claims Appendix" of the current wording of all pending claims.

Claims 1-6, 25 and 26 were rejected under Section 112 as being based on a nonenabling disclosure, or in conflict with the disclosure, because "the sliding motion, as originally disclosed, is not between the face and the first joint surface but between the face and the second or unresected joint surface".

The present application states that the invention is directed to a bioresorbable implant configured for positioning between articular joint surfaces, *at least one* of the joint surfaces being an exposed cancellous joint surface, as is discussed on page 7, lines 10-11. By implication, the other joint surface can also be an exposed surface.

With respect to the disclosure concerning an animal study that was performed to observe the invention in more detail, the specification states with reference to Figs. 3A-3F that the convex, dome surface 16 of humeral head 14 was removed as is shown in Fig. 3C. "The PLA implant 23 ... was mounted to resected head 14 of the humerus with the rounded, domed head 24 of implant 23 with a face reconstituting the rounded surface of the humeral head, and stem 26 of implant 23 locking into cavity 21 ...." (application page 7, lines 27-31). In the paragraph bridging pages 7 and 8 of the present application, the resection of the concave surface 30 of the shoulder joint is described. The application states:

> "Again using power driven burr 22, the normal articular cartilage on joint surface 30 was removed down to raw subchondral or cancellous bone to create a concave resected joint surface 34. The dislocated shoulder joint was then reduced, that is, brought back together with head 24 of implant 23 *abutting resected surface 34*. The wound was then closed. Implant 23 brought into direct contact with this raw socket surface 34 simulated an arthritis. Therefore, *head 24 of implant 23 would move against this raw bony surface 34* ...." (italics added)

As the foregoing quotation from the application makes clear, the implant surface, e.g. head 24 of implant 23, moves relative to the raw bony surface 34. The end result of this procedure was "a smooth, white surface where there had been raw cancellous or subchondral bone at the time of the original surgery" (page 8, lines 19-21).

As the foregoing demonstrates, this application describes repeatedly that there is motion, e.g. sliding motion, between the face of the implant and the resected joint surface. This is again repeated on page 9 of the application, which states (lines 30-34):

> "The rabbit studies provide experimental support for the concept that a resected joint surface with a bioresorbable inert implant *allowed to move against resected surface 20* will stimulate the normal healing process of fibroplasia to fibrocartilage."

On page 10, lines 31-33, the application states:

> "However, what appears to be necessary is that a resected surface **must rub against the bioabsorbable implant** to create the fibrocartilage."

There is no question, the application unequivocally states that the face of the resorbable implant moves relative to a resected bone surface. Applicant therefore urges that the Section 112 rejection of the claims as being in conflict with the disclosure be retracted.

The claims were principally rejected for anticipation or obviousness over Cohen because Cohen was viewed as disclosing to expose cancellous bone surface and then allow sliding motion between ball (4) of Cohen and the resected bone surface. The Office Action notes that ball (4) might be viewed as not providing a sliding surface because it is not explicitly stated as providing such. Nevertheless, the Office Action "posits that one viewing this embodiment would be led to the conclusion that the ball (4) obviously functions as a stop and sliding surface for the resected bone ends". Applicant disagrees.

All claims recite that the bioresorbable implant of the present invention must permit "slidable motion between the face and the first joint surface" (claim 1), the other independent claims 8 and 24-26 containing similar but not identical recitations, all to the effect that there must be relative slidable motion between the resected joint surface and the corresponding faces of the implant.

The present invention is directed to biologically reconstituting natural cartilage lost due to arthritis, trauma and the like with fibrocartilage that is a suitable joint (movement) surface for at least non-weight-bearing joints such as, for example, knuckle joints or the base of the thumb. The present invention seeks resurfacing cancellous bone surfaces with a layer of fibrocartilage that will permit a person to make normal use of the joint. The specification further states (page 3, lines 31-38):

> "The basic cell of healing is called the fibroblast and will develop at any site of injury and is the transformation of a normal blood clot. The fibroblast will go through a series of histological microscopic changes called fibroplasia. The fibroblast on a surface where there is constant motion will

change and develop into an entity known as fibrocartilage. This is white, smooth and looks very much like cartilage."

Thus, the present invention maintains the mobility of a joint (which has lost its natural cartilage) by promoting the generation of a fibrocartilage layer over the resected bone surface. To function substantially like the natural joint, that layer must have a smooth surface that can slidably move relative to an opposing surface—initially, relative to the opposing face of the implant and, after the resorption of the implant, relative to the opposing joint surface (which may be natural cartilage or another fibrocartilage grown in accordance with the present invention). To attain this, constant motion between the opposing surfaces must be maintained. Each independent claim specifically recites that there must be slidable motion between the resected cancellous bone surface (over which fibroblast and later fibrocartilage will form) and the associated face of the resorbable implant.

In view of the foregoing, applicant requests the retraction of the rejection of the claims for being based on a nonenabling disclosure, or for being in conflict with the disclosure.

Cohen discloses joint implants for the lesser digits and metatarsal phalangeal joints of a foot by first resecting opposing bone ends to expose cancellous bone. An implant 70 (Fig. 10) has a ball (4) (Fig. 1) and solid rods (2) which are integral with and project in opposite directions from the ball. The solid rods are inserted into holes drilled into the respective resected bones. After the solid rods of the implant have been inserted in the drilled holes, ball (4) maintains a spacing between the opposing, resected bone ends. Over time, fibrous tissue forms around the implant and eventually replaces it. Thus, with the implant in place, the opposing resected bone ends (illustrated in Fig. 10) are kept spaced apart by the implant, while the solid rods extend into the previously drilled holes in the bones. Ball (4) determines the size of the gap or spacing between the resected bone ends.

With the implant of Cohen, **there is no possibility that the opposing resected surfaces of the bones can slidably move relative to each other**. Solid rods (2) are substantially immovably anchored in the respective holes drilled into the opposing bones. When the bones are moved together (following completion of the operation), ball (4) between the opposing resected bone surfaces is not a slide surface or a pivot point. It is merely a

longitudinal spacer. To move one bone relative to the other, at least one of the solid rods necessarily has to be deformed. Absent such deformation, there is no possibility for the opposing bones to move with respect to each other because implant 70 provides a **rigid connection**.

Further, the ball located between and engaged by the opposing bones does not constitute a surface with respect to which one or the other bone may slide pivotally. To slide pivotally, it would be necessary to deform at least one of the two solid rods projecting from the ball through an angle which has to correspond in direction and magnitude to the angle of rotation about which the bones are to move with respect to each other. This is an impossibility and, if attempted, would damage (e.g. break) one or both of the bones in which one or both of the solid rods are anchored.

Thus, applicant completely disagrees with the observation in the above-referenced Office Action that Cohen would lead one to the "conclusion that the ball (4) obviously functions as a stop and sliding surface for the resected bone ends". Applicant agrees that the ball serves as a stop. Contrary to the assertion in the Office Action, it is **impossible** for the ball to act as a sliding surface because the solid rods anchored in the opposing bones prevent relative slidable motion between the ball (or any other part of the implant) and the bone(s).

Applicant noted the comment in the Office Action that "since the joint can flex and extend with the implant in place (see Col. 4, lines 38-39) that sliding on the ball (4) face would occur". As demonstrated above, given the structure and geometry of the implants disclosed in Cohen, sliding between the ball and the resected bone surfaces is an impossibility. In this context, applicant further points out that the statement in Cohen that "flexion and extension of the joint should not result in dislocation of the implant" has been misinterpreted. The Cohen patent does not state what flexion and extension is referred to. It is conceivable, for example, that flexion and extension by an adjacent joint is referred to. The absolute fact, however, remains that Cohen discloses a structure which is incapable of permitting flexion or extension of the joint into which implant 70 (Fig. 10 or Fig. 11) has been implanted.

In addition, any relative motion between the implant (i.e. ball (4)) and the resected bone surface(s) can only be due to some possible looseness of the solid rod in the hole drilled into the bone. Such a motion is an uncontrolled motion which cannot and does not encourage the formation of fibrocartilage joint surfaces which are complementary to the opposing implant surface (as recited in claims 5 and 24, for example) so that initial blood clots can undergo fibroplasia to ultimately result in fibrocartilages which have opposing, cooperating and relatively slidable surfaces. Cohen has nothing to do with growing fibrocartilage over resected bone surfaces. Cohen is solely concerned with forming a body of fibrous scar tissue between the opposing resected bone surfaces which ball (4) keeps spaced apart while the scar tissue forms. There is no intent by Cohen, and no disclosure in Cohen, of forming slidably movable surface layers for a bone joint. Any motion between the bones that might occur in Cohen is, at most, accidental and uncontrolled and in no event capable of generating a layer of fibrocartilage over a resected bone surface which can slidably interact with an opposing face or surface. Reading such disclosure into Cohen is no more than a hindsight reconstruction of Cohen based not on what is disclosed in Cohen, but what is set forth in the present application. Such hindsight rejections are inappropriate.

Thus, Cohen does not anticipate the pending claims or render them obvious. Applicant therefore submits that all claims are in condition for allowance. The issuance of a formal notification to that effect at an early date is requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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CLAIMS APPENDIX

1. A method for treating a joint having first and second mating joint surfaces comprising the following steps:

removing at least a portion of the first joint surface to expose a cancellous bone surface;

selecting a totally bioresorbable implant having a face adapted to face the removed portion of the first joint surface;

placing the bioresorbable implant between and in contact with the first and second joint surfaces so that the face is opposite the first joint surface and the implant initially keeps said exposed cancellous bone surface spaced apart from the second joint surface while permitting slidable motion between the face and the first joint surface; and

using the joint;

whereby the cancellous bone surface initially forms fibroblast at the first joint surface which progresses into fibrocartilage as the implant is resorbed so the fibrocartilage effectively replaces the implant during such resorption.

2. The method of claim 1 further comprising the step of selecting the bioresorbable implant made of a polymer of lactic acid.

3. The method of claim 2 wherein the selecting step is carried out by selecting a lactic acid copolymer.

4. The method of claim 1 further comprising the steps of:

estimating the period time it will take for the fibroblast to progress into fibrocartilage; and

selecting the bioresorbable implant of a size, shape and material according to said period of time.

5. The method of claim 1 further comprising the step of ensuring the exposed cancellous bone surface and the face of the bioresorbable implant placed against said cancellous bone surface have complementary surface shapes.

6. The method of claim 5 wherein the ensuring step includes the step of selecting curved surface shapes as said complementary surface shapes.

8. A method for treating a substantially non-weight bearing arthritic joint having first and second mating joint surfaces comprising the following steps:

removing at least a portion of the first and second joint surfaces to expose first and second cancellous bone surfaces;

selecting a bioresorbable implant having first and second implant faces corresponding to the first and second cancellous bone surfaces;

placing the first and second implant faces of the bioresorbable implant between and against the first and second exposed cancellous bone surfaces so as to permit relative slidable motion between the first and second faces and the first and second joint surfaces; and

using the joint;

whereby fibroblast is initially formed which progresses into fibrocartilage at each said cancellous bone surface as the implant is resorbed, thereby effectively replacing the implant during such resorption.

9. The method of claim 8 wherein the selecting step is carried out by selecting said bioresorbable implant having a generally semi-spherically shaped joint surface as the first implant surface.

10. The method of claim 8 further comprising the steps of:

estimating the period of time it will take for the fibroblast to progress into fibrocartilage; and

selecting the bioresorbable implant of a size and material according to said period of time.

24. (four times amended) A method for treating at least one degenerated surface on a cancellous bone, the surface being one of first and second relatively movable surfaces defining a body joint, the method comprising the steps of resecting the bone to form a cancellous bone surface, placing a bioresorbable implant between the first and second surfaces to thereby space the surfaces apart, providing the implant with at least one face which is opposite and shaped complementary to at least one of the first and second surfaces so that the

implant can slidably move relative to the at least one of the first and second surfaces, allowing the face to move relative to the at least one of the first and second surfaces, permitting growth of fibroblast on the cancellous surface and conversion of the fibroblast into fibrocartilage during the allowing step, maintaining a spacing between the body joint defining surfaces during the permitting step, and waiting for the body to gradually resorb the implant during the permitting step so that, upon resorption of the implant, the fibrocartilage forms at least one of the body joint defining surfaces.

25. (twice amended) A method for treating a joint having first and second mating joint surfaces comprising the following steps:

removing at least a portion of the first joint surface to expose a cancellous bone surface;

placing a bioresorbable implant between and in contact with the first and second joint surfaces so the implant initially keeps said exposed cancellous bone surface spaced apart from the second joint surface;

providing the implant with a face which is opposite the first surface;

permitting relative slidable motion between the face and the first surface; and

using the joint, which includes slidably moving the face relative to the first surface;

whereby the cancellous bone surface initially forms fibroblast which progresses into fibrocartilage as the implant is resorbed so the fibrocartilage effectively replaces the implant during such resorption;

estimating the period of time it will take for the fibroblast to progress into fibrocartilage; and

selecting the bioresorbable implant of a size, shape and material according to said period of time.

26. (twice amended) A method for treating a joint having first and second mating joint surfaces carried by cancellous bone comprising the following steps:

removing at least a portion of the first joint surface to expose a cancellous bone surface;

forming a cavity into the medullary canal of the cancellous bone carrying the second joint surface;

selecting a bioresorbable implant configured to fit between the first and second joint surfaces, the implant having a face, a backside and a stem portion extending from the backside and configured to fit within said cavity;

inserting the stem portion into the cavity and placing the bioresorbable implant between the first and second joint surfaces so the implant initially keeps said surfaces spaced apart and the face is slidably movable relative to the first joint surface; and

using the joint, including slidably moving the face relative to the first joint surface;

whereby the cancellous bone surface initially forms fibroblast which progresses into fibrocartilage as the implant is resorbed so the fibrocartilage effectively replaces the implant during such resorption.